

## **Remarks**

### ***I. Status of the Claims***

Reconsideration of this Application is respectfully requested.

By the foregoing amendments, claims 62, 64, and 89-109 are cancelled without prejudice to or disclaimer of the subject matter therein, and claim 1 is sought to be amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Upon entry of the foregoing amendments, claims 1-10, 22-30, 43-61, 65-68, 73-88 and 138 are pending in the application, with claim 1 being the independent claim.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### ***II. Oath/Declaration***

Section 5 of the Office Action at pages 2-3, stated that the oath or declaration was defective and a new oath or declaration in compliance with 37 C.F.R. § 1.67(a) was required. According to the Office Action, the oath/declaration is defective because "the specification indicates priority to several provisional applications. However, the oath/declaration does not acknowledge the priority to the provisional applications." Office Action at page 2.

Applicants assert that the oath or declaration as filed complies with 37 C.F.R. § 1.63. First, 37 C.F.R. § 1.63(a) requires that an oath or declaration filed as part of a non-provisional application must (1) be executed, (2) identify each inventor by full

name, (3) identify the country of citizenship of each inventor, and (4) state that the person making the oath or declaration believes the named inventor(s) to be the original and first inventors.

Second, 37 C.F.R. § 1.63(b) requires that (1) the oath or declaration identify the application to which it is directed, (2) state the person making the oath or declaration has reviewed and understands the content of the application, and (3) state that the person making the oath or declaration acknowledges the duty to disclose to the Office all known material information.

Third, 37 C.F.R. § 1.63(c) requires that the oath or declaration (1) identify the mailing address and the residence of an inventor, if an inventor lives at a location which is different from where the inventor customarily receives mail, and (2) identify any *foreign* application for patent, for which a claim for priority is made pursuant to § 1.55, and any *foreign* application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month, and year of its filing.

Fourth, 37 C.F.R. § 1.63(d) states that a newly executed oath or declaration is not required in a continuation or divisional application, provided that (1)(i) the prior application contains an oath or declaration, (ii) the continuation or divisional was filed by all or fewer than all of the inventors named in the prior application, (iii) there is no new matter in the specification or drawings of the present application that would have been new matter in the prior application, and (iv) a copy of the prior oath or declaration is submitted with the continuation or divisional; (2) the copy of the oath or declaration is accompanied by a statement requesting the deletion of any names of persons who are not

inventors in the continuation or divisional application; (3) a copy of the executed oath or declaration accorded status under § 1.47 must be accompanied by (i) a copy of the decision granting a petition to accord status, and (ii) a copy of a subsequently executed oath or declaration filed by an inventor or legal representative who refused to join in the prior application; and (4) where the power of attorney changed during prosecution of the prior application, the change in power of attorney must be identified in the continuation or divisional application.

Finally, 37 C.F.R. § 1.63(e) requires that a newly executed oath or declaration must be filed in any continuation-in-part application. *Hence, nowhere in 37 C.F.R. § 1.63 is there a requirement for an oath or declaration to refer to U.S. provisional priority applications.* Consequently, the priority document does not need to be included in the oath or declaration and, as such, Applicants need not file a supplemental oath or declaration under 37 C.F.R. § 1.67(a). Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

### ***III. The Rejection Under 35 U.S.C. § 112, First Paragraph***

In section 11 of the Office Action at page 4, claims 1-10, 22-30, 43-62, 64-68, 73-88, and 138 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Office Action alleged that

the claimed invention contains no identifying characteristics regarding the identified polynucleotide or the library of insert polynucleotides used. Additionally, the narrow scope of examples directed to the use of specific vaccinia virus vectors in tri-molecular-recombination method, which are clearly not representative of the scope of the presently claimed method.

Office Action at page 6. Applicants respectfully disagree and traverse this rejection as applied to the claims as amended.

Applicants respectfully point out that the test for written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02.

The Examiner contends that the specification "is directed to the use of specific Vaccinia virus vectors in trimolecular-recombination method, which clearly do not provide an adequate representation regarding the open ended claimed method for selecting a target polynucleotide of the instant claims." Office Action at page 5.

Applicants disagree with this statement as applied to the claims as amended for at least the following reasons. First, in an effort to facilitate prosecution, and not in acquiescence to the Examiner's rejection, Applicants have cancelled claims 62 and 64; and amended claim 1 to recite "wherein said library is constructed in a poxvirus vector and wherein expression of said target polynucleotide directly or indirectly promotes cell death."

Second, with respect to the poxvirus, it is true that the production of a specific poxvirus library, *i.e.*, vaccinia virus, is indeed described in the specification. However, Applicants respectfully point out that the specification also describes numerous other poxviruses that could be used in the claimed method including avipoxvirus, capripoxvirus, leporipoxvirus, and suipoxvirus. *See* specification at paragraph [0293] (page 46).

Third, Applicants respectfully submit that the Examiner has mischaracterized the specification with respect to the use of the "trimolecular recombination method in the method of identifying the target polynucleotide." Office Action at pages 4-5. While the specification does indicate that other methods of constructing libraries using vaccinia virus vectors, *e.g.*, direct ligation and homologous recombination, result in a relatively low recombination efficiency and titer (*see* Specification at paragraphs [0310] (page 52), it does not say that methods such as direct ligation or modified homologous recombination cannot be used to generate vaccinia virus expression libraries, as implied by the Examiner. Furthermore, while these methods may not be as efficient as trimolecular recombination, there is no requirement in the claims for a particular titer or recombination efficiency. Thus, contrary to the Examiner's assertion, the specification does not require that the "tri-molecular recombination method" be used in the claimed method of identifying a target polynucleotide. Hence, given the disclosure in the present specification, Applicants respectfully submit that the claims are not overly broad, and that one of ordinary skill could reasonably conclude that the inventors had possession of the claimed methods in the specification as filed.

The Examiner further contends that "the claimed invention contains no identifying characteristics regarding the identified polynucleotide." Office Action at page 6. Applicants respectfully assert that it is not necessary to describe the identifying characteristics of potential target nucleotides because the claims are not directed to these target polynucleotides *per se*, but rather they are directed to a method of selecting them, without any foreknowledge of what their identifying characteristics may be. Nevertheless, the specification describes numerous species of potential target

polynucleotides including tumor suppressive genes, apoptosis-inducing genes, cell proliferation genes, genes that arrest cell cycle, essential genes, oncogenes, and genes that induce expression of a suicide gene construct that could be identified by the claimed method. *See* specification at paragraphs [0408]-[0423] (pp. 84-89), [0464]-[0485] (pp. 101-108), [0510]-[510] (pp. 116-117), and [0516]-[0538] (pp. 119-127). The specification also describes numerous suicide genes and toxic gene products, besides diphtheria toxin A subunit, that can be used to identify target polynucleotides such as, p53, *Pseudomonas* exotoxin A chain, ricin A chain, abrin A chain, modeccin A chain, and alpha-sarcin. *See* specification at paragraph [0455] (p. 99), and in Examples 7, 11, 12, and 14. Thus, contrary to the Examiner's assertion, the specification discloses numerous species of potential target polynucleotides which may be identified by the claimed method.

In addition, the Examiner states that no working examples of the instantly claimed method have been described. *See* Office Action at page 5. Applicants note that a requirement of "working examples" is an incorrect application of the law with respect to the written description requirement. The written description requirement is met if the specification discloses relevant identifying characteristics sufficient to describe the claimed invention in such terms that a skilled artisan would recognize that the applicant was in possession of the claimed invention. *See* M.P.E.P. § 2163(II)(A).

Based on the comments above, Applicants assert that the disclosure adequately describes the claimed method and that one of ordinary skill in the art could reasonably conclude that the inventors had possession of the claimed method when the application was filed. Thus, the written description requirement has been satisfied. To focus on a

preferred embodiment, as did the Office Action, is to ignore the vast majority of the detailed description, which describes numerous other embodiments. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

**IV. Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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